DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 2, 2015

Otto Bock Healthcare Products GmbH
Rene Urtz
Regulatory Affairs Specialist
Brehmstrabe 16
1110 Vienna
AUSTRIA

Re: K141812
Trade/Device Name: MyGait Stimulation System
Regulation Number: 21 CFR 882.5810
Regulation Name: External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Code: GZI, IPF
Dated: February 23, 2015
Received: February 27, 2015

Dear Mr. Urtz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141812

Device Name
MyGait Stimulation System

Indications for Use *(Describe)*
The stimulation system is intended to provide ankle dorsiflexion and knee flexion or extension in individuals with foot drop and thigh muscle weakness following an upper motor neuron injury or disease.
During gait, the stimulation system sends electric stimuli to muscles in the affected leg, initiating dorsiflexion of the foot and knee extension or flexion and may thus improve the individual's gait. The stimulation system may also prevent or retard atrophy caused by inactivity, facilitate muscle reeducation, maintain or improve the range of motion in the joints and promote local blood circulation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(K) SUMMARY

1 Submitter Information

Manufacturer:	Otto Bock Healthcare Products GmbH
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Date Prepared:	March 31, 2015

2 Device Information

Trade Name:	MyGait® Stimulation System
Common or Usual Name:	Stimulator, Neuromuscular, External
Classification Name:	External functional neuromuscular stimulator
	(21 CFR 882.5810)
Classification Product Code:	GZI (stimulator, neuromuscular, external functional)
Subsequent Product Code:	IPF (stimulator, muscle, powered)

3 Identification of Legally Marketed Predicate Devices

Name:	Walkaide
Manufacturer:	Innovative Neurotronics, Inc.
510k Number:	K123972
Date Cleared:	April 4th, 2013

Name:	Empi 300pv
Manufacturer:	Empi, Inc
510k Number:	K021100
Date Cleared:	June 18th, 2002

Name:	NESS L300 Plus System*
Manufacturer:	Bioness Neuromodulation Ltd.
510k Number:	K103343
Date Cleared:	April 29th, 2011

* Primary predicate

4 Indications for Use

The stimulation system is intended to provide ankle dorsiflexion and knee flexion or extension in individuals with foot drop and thigh muscle weakness following an upper motor neuron injury or disease.
During gait, the stimulation system sends electric stimuli to muscles in the affected leg, initiating dorsiflexion of the foot and knee extension or flexion and may thus improve the individual's gait. The stimulation system may also prevent or retard atrophy caused by inactivity, facilitate muscle reeducation, maintain or improve the range of motion in the joints and promote local blood circulation.

5 Device Description

The MyGait® Stimulation System is a battery-operated two-channel stimulator and was developed exclusively for everyday use during walking in an everyday environment.

The patient wears a wireless heel switch in a special sock. If the user is not able to put sufficient weight on the affected leg, he or she can wear the heel switch on the other foot.
The heel switch registers heel lift and ground contact and thus the swing and stance phase. It transmits the information to the stimulator wirelessly.

The stimulator is located in a cuff that holds the electrodes. It is easy to put on, even with only one hand. The correct placement of the electrodes is achieved by the cuff. The stimulator delivers the electrical stimulation to the common peroneal nerve. The nerve stimulates the muscles for controlled dorsiflexion of the foot during the swing phase.

The second channel can be used independently of the first channel to provide stimulation to the knee flexors or knee extensors in patients with thigh muscle weakness.

Using the wireless remote control, the patient can control and adjust the stimulator settings. When the patient sits for an extended period, the sleep mode helps save energy.

The adjustment tool enables qualified personnel to adjust the stimulation parameters to the patient's individual needs. Stimulation parameters are used to affect movements in the foot. Examples of stimulation parameters are current, pulse width and shape, frequency, stimulation timing.

The "MyGait Soft" PC software is used to manage and analyze gait analysis data and stimulation parameters. The data is loaded from the stimulator to the PC using the adjustment tool. The stimulation parameters can be restored to the stimulator from the PC.

6 Substantial Equivalence Discussion

6.1 Indications for Use

	New Device	Predicate Device	Predicate Device	Predicate Device
510k Number	K141812	K123972	K021100	K103343
Device Name, Model	MyGait	WalkAide	Empi 300pv	NESS L300 Plus System
Manufacturer	Otto Bock Healthcare Products GmbH	Innovative Neurotronics, Inc.	Empi, Inc	Bioness Neuromodulation Ltd.
Indications for Use	The stimulation system is intended to provide ankle dorsiflexion and knee flexion or extension in individuals with foot drop and thigh muscle weakness following an upper motor neuron injury or disease. During gait, the stimulation system sends electric stimuli to muscles in the affected leg, initiating dorsiflexion of the foot and knee extension or flexion and may thus improve the individual's gait. The stimulation system may also prevent or retard atrophy caused by inactivity, facilitate muscle reeducation, maintain or improve the range of motion in the joints and promote local blood circulation.	Summary Statement The Innovative Neurotronics WalkAide External Functional Neuromuscular Stimulator (WalkAide System) is intended to address the lack of ankle dorsiflexion in patients who have sustained damage to upper motor neurons or pathways to the spinal cord. During the swing phase of gait, the WalkAide System electrically stimulates the appropriate muscles that cause ankle dorsiflexion and may thus improve the patient's gait. Medical benefits of Functional Electrical Stimulation (FES) may include prevention, retardation of disuse atrophy, increased local blood flow, muscle re-education, and maintained or increased joint range of motion.	Summary Statement The 300 PV is a multifunction electrotherapy device with various treatment modes that allow for neuromuscular electrical stimulation (NMES), transcutaneous electrical nerve stimulation (TENS), interferential current stimulation (IFS) and functional electrical stimulation (FES). As a NMES device, the 300 PV is indicated for the following conditions: Re-educating muscles Relaxation of muscle spasm Increasing local blood circulation Retarding or preventing disuse atrophy Maintaining or increasing range of motion. Prevention of venous thrombosis of the calf muscles immediately after surgery. As a TENS device, the 300 PV is indicated for the following conditions: Symptomatic relief and management of chronic, intractable pain. Adjunctive treatment for post-surgical and post-trauma acute pain. As an IFS device, the 300 PV is indicated for the following conditions: Symptomatic relief of acute pain Symptomatic relief and management of chronic pain. As a FES device, the 300 PV is indicated for the following condition: Stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient's gait.	Summary Statement The NESS L300 Plus System is intended to provide ankle dorsiflexion and knee flexion or extension in individuals with foot drop and thigh muscle weakness, following an upper motor neuron injury or disease. During gait, the L300 Plus System electrically stimulates muscles in the affected leg to provide dorsiflexion of the foot and knee flexion or extension, thus it may improve the individual's gait. The L300 Plus System may also: * Facilitate Muscle re-education * Prevent/retard disuse atrophy * Maintain or increase joint range of motion * Increase local blood flow

Table 1 - Comparison Table of Indications for Use

6.2 Technological Characteristics

6.2.1 Basic Unit Characteristics

	New Device	Predicate Device	Predicate Device	Predicate Device
510k Number	K141812	K123972	K021100	K103343
Device Name, Model	MyGait	WalkAide	Empi 300pv	NESS L300 Plus System
Manufacturer	Otto Bock Healthcare Products GmbH	Innovative Neurotronics, Inc.	Empi, Inc	Bioness Neuromodulation Ltd.
Power Sources				
Battery	built in	replaceable	replaceable	built in
# of batteries	1	1	2	1
type	Lilon	Alkaline	Alkaline	Lilon
size	3.7V, 1100mAh	AA, LR6	AA, LR6	3.7 V, 750mAh
Method of Line Current Isolation	Medical Class II Power Adapter	n/a	n/a	Unknown
Patient Leakage Current				
normal condition	<1µA	Unknown	Unknown	Unknown
Single Fault condition	<1µA	Unknown	Unknown	Unknown
Number of Output Modes	2	1	5	2
Number of Output Channels	2	1	2	2
Synchronous or Alternating	Synchronous or alternating	n/a	Unknown	Unknown
Method of Channel Isolation	n/a	n/a	Unknown	Unknown
Regulated Current or regulated voltage	Regulated Current	Constant Voltage	Regulated Current/Voltage	Regulated Current
Software/Firmware/ Microprocessor Control	yes	yes	yes	yes
Automatic Overload Trip	yes	no	unknown	yes
Automatic No-Load Trip	yes	no	unknown	no
Automatic Shut Off	no	no	unknown	no
Patient Override Control	ON/OFF Button	Amplitude Control Knob	ON/OFF Button	Intensity adjustment buttons and ON/OFF Buttons
Indicator Display				
On/Off Status	yes	yes	yes	yes
Low Battery	yes	yes	yes	yes
Voltage/Current Level	no	Control Knob	yes	no
Timer Range (min)	5 to 120min in steps of 5 min	1 to 30min steps of 1 min	5-60 or unlimited	1-60
Compliance with Voluntary Standards	IEC 60601-1:2005 +A1:2012 IEC 60601-1-11:2010 IEC 60601-2-10:2012 IEC 60601-1-2:2007	IEC 60601-1 3rd Ed IEC60601-1-2:2007 IEC 60601-2-10:1987+A1	Unknown	Unknown

Compliance with 21 CFR 898	Yes	Yes	Unknown	Unknown
Weight	78g	87,6	226g	45 g
Dimensions (in.) (WxHxD)	3.26 x 2.08 x 0.71	2.4 x 3.25 x 0.81	1.26 x 3.3 x 4.5	3 x 1.7 x 0.57
Housing Material	ABS	ABS	unknown	Unknown
Accessories	Wireless foot switch (with failsafe mode), wireless remote control	Wired foot switch	Wired external trigger	Wireless foot switch (with failsafe mode), wireless remote control
Procedure for setting up stimulation parameters	Wireless via MyGait Adjustment Tool	Wireless via PC Software, Bluetooth adapter and Walklink unit	Via stimulation device	Wireless via PDA
Description of PC-Software	Download and display of gait evaluation data, up/download of stimulation parameters	Download and display of gait evaluation data, up/download of stimulation parameters, setting up stimulation parameters	n/a	Download and display of gait evaluation data, up/download of stimulation parameters, setting up stimulation parameters

Table 2 - Comparison Table of Basic Unit Characteristics

6.2.2 Output Specifications

	New Device	**Predicate Device**	**Predicate Device**	**Predicate Device**
510k Number	K141812	K123972	K021100	K103343
Device Name, Model	MyGait	WalkAide	Empi 300pv	NESS L300 Plus System
Manufacturer	Otto Bock Healthcare Products GmbH	Innovative Neurotronics, Inc.	Empi, Inc	Bioness Neuromodulation Ltd.
Waveform Monophasic or biphasic Symmetrical or Asymmetrical	Biphasic Symmetrical or asymmetrical	Biphasic Asymmetrical	Biphasic Asymmetrical	Biphasic Symmetrical or asymmetrical
Shape	Rectangular	Unknown	Unknown	Rectangular
Maximum output voltage, +/- %				
@ 500	45V +-10%	Unknown	Unknown	Unknown
@ 1k	90V +-10%	121V +-10%	140V +/- 10%	80V (tolerance unknown)
@ 2k	120V +-10%	Unknown	Unknown	Unknown
@ 10k	n/a (no stimulation possible at 10k)	Unknown	Unknown	Unknown

Maximum output current, +/- %				
@ 500	90mA (+/- 10%)	206,8mA peak (+/- 5%)	100mA (+/- 20%)	80mA (tolerance unknown)
@ 1k	90mA (+/- 10%)	121mA	Unknown	Unknown
@ 2k	60mA (+/- 10%)	Unknown	100mA (+/- 20%)	60mA (tolerance unknown)
@ 10k	n/a (no stimulation possible at 10k)	Unknown	Unknown	Unknown
Pulse width, all possible discrete settings	Symmetrical: 50 to 400µs in steps of 50µs Asymmetrical: pos.: 50 to 400µs in steps of 50µs Neg.: 200 to 1600µs in steps of 100µs	25, 50, 100, 150, 200, 250, 300µs	50-400µs (± 10% ≥ 100 µsec, ± 10 µsec < 100µsec)	Symmetrical: 100,200,300µs Asymmetrical: pos: 100,200,300µs neg.: 400,800,1200µs
Frequency, all possible discrete settings	10 to 80Hz in 1Hz steps	16.7, 20, 25, 33.3 Hz	2-150 Hz	20, 25, 30, 35, 40, 45
For interferential modes only: Beat Frequency (Hz)	n/a (no interferential mode)	n/a	n/a	n/a
For multiphasic waveforms only	n/a (no multiphasic waveforms)	n/a	n/a	n/a
Symmetrical phases	n/a (no multiphasic waveforms)	n/a	n/a	n/a
Phase Duration (include units)	n/a (no multiphasic waveforms)	n/a	n/a	n/a
Net Charge (µC per pulse) if zero, state method of achieving zero net charge @500	0µC Balanced pulses	Unknown	Unknown	0µC Balanced pulses
max. pulse charge @500	36µC	41,2µC	40µC	24µC
max. RMS current density (mA/cm2) @500	1,51	2,62	6,79	0,83
max. power density (W/cm2) @500	0,024	0,027	0,17	0,00536
BurstMode				
Pulses per burst	Burst length and pps dependent	Burst length and pps dependent	Burst length and pps dependent	Burst length and pps dependent
Bursts per second	Depends on ON and OFF times	Depends on ON and OFF times	Depends on ON and OFF times	Depends on ON and OFF times
Burst Duration (sec)	1 to 4 sec in 0.1sec steps	1 to 5 sec in 1 sec steps	Unknown	4 to 20 sec in 1sec steps
Duty Cycle	Depends on ON and OFF times	Depends on ON and OFF times	Depends on ON and OFF times	Depends on ON and OFF times
On Time	1 to 4 sec in 0.1sec steps	1 to 5 sec in 1sec steps	Unknown	4 to 20 sec in 1sec steps
Off Time	1 to 30 sec in 1sec steps	1 to 10 sec in 1sec steps	Unknown	4 to 60 sec in 1sec steps
Additional Frequencies (if applicable)	n/a (no additional frequencies)	n/a	n/a	n/a

Table 3 - Comparison Table of Output Specifications

6.3 Substantial Equivalence Discussion

6.3.1 Discussion on basic unit characteristics

Power sources

The MyGait stimulator has one built-in LiIon battery (3.7 V, 1100mAh), the same technology as the predicate device NESS L300 Plus (3.7V, 750mAh). An external medical class II power adaptor is used to charge the battery and to isolate the user from AC line current.

Patient Leakage current

The patient leakage is <1µA in normal condition and single fault condition was successfully tested according to IEC 60601-1.

Output channels

The MyGait stimulator can be used in one-channel operation or two-channel operation as well the predicate devices Empi 300pv and NESS L300 Plus can be used. It is possible to adjust the timing parameters of both channels. So therefore, a synchronous or an alternating stimulation related to the two channels is possible.

Output characteristics

The pulse generation is controlled by a microprocessor constant current based. All of the predicate devices are microprocessor controlled. In addition, NESS L300 Plus and Empi 300pv are constant current based too.

Automatic no-load trip

The MyGait has an automatic no-load trip in contrast to the predicate devices. An automatic no-load trip takes place via impedance measuring. It is a common feature of stimulation devices which improves the usability because stimulation is only possible, if an output load is connected.

Patient override control

The Override control is controlled by an ON/OFF button like the NESS L300 Plus and the Empi 300pv devices.

Indicator Display

The MyGait stimulator indicates the On/Off state and a low battery by a LED. The current level is displayed on the MyGait remote control. In principle, it is the same procedure as the NESS L300 Plus and the WalkAide offers.

Timer range

MyGait´s training programme timer range is adjustable from 5 to 120 minutes in steps of 5 minutes. It is within the range of the predicate devices. The timer range goes from WalkAide´s 5 to 30 minutes to Empi 300pv´s 5 to 60 minutes or unlimited.

Accessories

The heel switch transmits its data wirelessly to the stimulator. Loss of communication will be detected and will trigger a failsafe mode. This technology is similar to the predicate device NESS L300 Plus.

Procedure for setting up stimulation parameters

The MyGait adjustment tool is for setting up the stimulation parameters of the My Gait stimulator. The predicate devices NESS L300 Plus and WalkAide have the same wireless principle.

Conclusion

The basic unit characteristics are equivalent to the predicate devices as can be seen in the comparison table in chapter 6.2.1.

6.3.2 Discussion on output specifications

Waveform

The waveform of the MyGait is biphasic symmetrical or biphasic asymmetrical equal to the NESS L300 Plus. Innovative Neurotronics´ WalkAide and Empi Inc.´s Empi 300pv have biphasic asymmetrical pulses.

Maximum output voltage

The maximum output voltage rating of the MyGait is 45V at 500 Ohm and 120V at an output load of 2 KOhm. In general, the maximum output peak is 120 V regardless of the load. There are no parameters provided at an output load of 500 Ohm and 2 kOhm by the predicate devices. WalkAide provides a maximum output voltage of 121 V and NESS L300 Plus of 120 V. Empi has an output value of 140 V without load. Based on this information the conclusion is that the maximum output voltage of the MyGait is within the range of the predicate devices at 500 Ohm and 2 kOhm.

Maximum output current

The maximum output current of the MyGait is 90 mA at 500 Ohm and 60mA at a load of 2 kOhm. WalkAide´s maximum output peak current is listed with 206.8 mA at 500 Ohm. In addition, the NESS L300 Plus is listed with 90 mA at 500 Ohm and the Empi 300pv with 100 mA at 500 Ohm. At a load of 2 kOhm, the NESS L300 Plus is rated at 60 mA and the Empi 300pv at 100 mA. Based on this information the conclusion is that the maximum output current of the MyGait is within the range of the WalkAide and Empi 300pv devices.

Pulse width

The MyGait has the same positive pulse range width as the predicate Empi 300v.
In asymmetrical mode, the negative pulse width range of the MyGait is from 200µs to 1600µs. The NESS L300 Plus has a negative pulse width range from 400µs to 1200µs. The MyGait and the NESS L300 Plus have both a ratio of 1:4 between the positive and the negative pulse. The MyGait´s positive pulse width range is from 50µs to 400µs compared to the 100µs to 300µs of the NESS L300 Plus. Therefore the MyGait´s negative pulse range is from 200µs to 1600µs compared to the 400µs to 1200µs of the NESS L300 Plus. All of these pulse widths are similar and common stimulation parameters.

Frequency

The adjustable frequency range of the MyGait is from 10 to 80 Hz and within Empi 300pv´s range from 2 to 150 Hz. The WalkAide is selectable between 16.7, 20, 25 and 33.3 Hz and the NESS L300 Plus is selectable from 20 to 45 Hz in steps of 5 Hz.
Net charge

There is no net charge. Balanced pulses are used to achieve zero net charge. This is similar to the NESS L300 Plus.

Maximum pulse charge

The maximum pulse charge at 500 Ohm load is 36 µC compared to the 41.2 µC, 24 µC and 40 µC of the predicate devices. The value is within the range of the predicate devices and therefore equivalent.

Maximum RMS current density

The maximum RMS current at 500 Ohm load is 1.51 mA/cm^2 compared to the 2.62 mA/cm^2, 0.83 mA/cm^2 and 6.79 mA/cm^2 of the predicate devices. The value is within the range of the predicate devices and therefore equivalent.

Maximum power density

The maximum power density at 500 Ohm load is 0.024 W/cm^2 compared to the 0.027 W/cm^2, 0.00536 W/cm^2 and 0.17 W/cm^2 of the predicate devices. The value is within the range of the predicate devices and therefore equivalent.

On time

The on time of the MyGait in training mode is adjustable from 1 to 4 seconds in steps of 0.1 seconds. The on time of the WalkAide is selectable from 1 to 5 seconds in steps of 1 second and the NESS L300 Plus from 4 to 20 seconds in steps of 1 second. The adjustment of the MyGait is more precisely but within the range of the compared devices.

Off time

The off time in training mode of the MyGait is adjustable from 1 to 30 seconds in steps of 1 second. The off time of the WalkAide is selectable from 1 to 10 seconds in steps of 1 second and the NESS L300 Plus from 4 to 60 seconds in steps of 1 second. The values of MyGait are within the range of the compared devices.

The output specifications are equivalent to the predicate devices as can be seen in the comparison table in chapter 6.2.2.

6.3.3 Conclusion

The MyGait Stimulation System has the same indications for use and the same principle of operation as the WalkAide from Innovative Neurotronics Inc. cleared under 510(k) no. K123972, the NESS L300 Plus System from Bioness Neuromodulation Ltd. cleared under 510(k) no. K103343 and the Empi 300pv from Empi Inc. cleared under 510(k) no. K021100.

The MyGait Stimulation System was successfully tested for electrical safety according to IEC 60601-1 “Medical electrical equipment - Part 1: General requirements for basic safety and essential performance“, IEC 60601-1-11 “Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment”, IEC 60601-2-10 “Medical electrical equipment – Part 2-10: Particular requirements for the safety of nerve and muscle stimulators” and for electromagnetic compatibility according to IEC 60601-1-2 “Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests”.

The evaluation of the MyGait stimulation system does not raise any additional concerns regarding safety and effectiveness. Based on the equivalent indications for use and similar technological characteristics, Otto Bock Healthcare GmbH considers its MyGait Stimulation System to be substantially equivalent to the predicate devices.

The MyGait Stimulation System is safe and effective for its intended use.

7 Summary of Performance Testing

No.	Title	Version	Comments
IEC 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	2005 + A1:2012	Electrical Safety
IEC 60601-1-11	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	2010	
IEC 60601-2-10	Medical electrical equipment – Part 2-10: Particular requirements for the safety of nerve and muscle stimulators	2012	
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests	2007	Electromagnetic Compatibility
IEC 60529	Degrees of protection provided by enclosures (IP Code)	1999	Enclosure
ISO 10993-1	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process	2009	Biocompatibility
ISO 10993-5	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity	2009	
ISO 10993-10	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization	2009	
EN 980	Symbols for use in the labeling of medical devices	2008	Labeling Symbols
IEC 60721-3-2	Classification of environmental conditions Part 3: Classification of groups of environmental parameters and their severities - Section 2: Transport	1997	Shipping test
IEC 60068-2-1	Environmental testing Part 2-1: Tests – Test A: Cold	2007	
IEC 60068-2-2	Environmental testing Part 2-2: Tests – Test B: Dry heat	2007	
IEC 60068-2-30	Environmental testing Part 2-30: Tests – Test Db: Damp heat, cyclic (12 + 12-hour cycle)	2005	
IEC 60068-2-78	Environmental testing Part 2-78: Tests – Test Cab: Damp heat, steady state	2001	
IEC 60068-2-14	Environmental testing Part 2: Tests – Test N: Change of temperature	1986	
IEC 68-2-64 (EN 60068-2-64)	Environmental testing Part 2-64: Test methods – Test Fh: Vibration, broad-band random (digital control) and guidance	1993	
IEC 68-2-27 (EN 60068-2-27)	Environmental testing Part 2-27: Tests – Test Ea and guidance: Shock	1987	
IEC 68-2-32 (EN 60068-2-32)	Basic environmental testing procedures Part 2: Tests – Test Ed: Free fall	1990	